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PATENT & TRADEMARK OFFICE

PATENT
Customer No. 22,852
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Joseph C. CAUTHEN

Serial No.: **10/075,615** — Group Art Unit: 3738

Filed: **February 15, 2002** — Examiner: Chattopadhyay, U.

For: **SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT** — Confirmation No.: 2841

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF JOSEPH C. CAUTHEN UNDER 37 C.F.R. § 1.131

1. I, Joseph C. Cauthen, am the named applicant of the above-identified application. My Curriculum Vitae is attached as Exhibit A.

2. I also am the sole inventor of the subject matter described and claimed in the above-identified application, and I executed a Declaration to that effect on April 30, 2002 that has been filed in this application. As stated in that Declaration, this application claims the benefits under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/160,710, filed October 20, 1999 and 35 U.S.C. § 120 of U.S. Patent Application No. 09/484,706, filed January 18, 2000 and U.S. Patent Application No. 09/947,078, filed September 5, 2001. Exhibit B is a copy of the '710 provisional application.

3. I have been advised that the United States Patent & Trademark Office in an Office Action dated June 3, 2004 rejected certain claims of the above-identified application by applying the teachings of U.S. Patent No. 6,245,107 to Ferree (the Ferree patent) and separately U.S. Patent No. 6,224,630 to Bao et al. (the Bao patent) as prior art. Based on information and belief, the Ferree patent was filed on May 28, 1999 and the Bao patent was filed on May 29, 1998. Neither the Ferree patent nor the Bao patent claim foreign priority.

BEST AVAILABLE COPY

4. Prior to May 29, 1998 I conceived in this country the invention described and claimed in the application. As described further below, this conception is based on an actual surgery performed by me in the United States prior to May 29, 1998. More particularly, I conceived of a therapeutic or prophylactic device for treating a spinal disc annulus having an aperture, wherein the device comprises a biocompatible material for placement in and across the aperture such that said material forms a bridge subannularly to provide a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus.

5. My invention is described in an abstract that I prepared and submitted in advance of my participation as a presenter at a meeting of the Congress of Neurological Surgeons (CNS) held in Boston from October 30 to November 4, 1999. On April 15, 1999 an online abstract submission process was completed under my supervision, and the confirmation page containing that abstract was printed. A copy of that confirmation page printed on April 15, 1999 is attached hereto as Exhibit C.

6. More particularly, the abstract discusses a therapeutic or prophylactic device for use in intervertebral disc reconstruction to treat a disc having an aperture (*i.e.,* annular defect) in the wall of the annulus fibrosus, wherein the aperture provides a path for the migration of nucleus pulposus from the subannular space (*i.e.*, herniation), the device being a collapsible patch (*e.g.,* fascial autograft) that is inserted in and across the aperture, thereby at least partially spanning the aperture subannularly with the patch. The abstract discusses placing the fascial tissue in the subannular loop of the sutures used to close the annulotomy incision. The fascial tissue after deployment was of a dimension larger than the defect to be secured by the subannular suture loops and not be pulled through the annular opening. Further, the fascial tissue was of a first dimension permitting it to be pushed through the annular defect to introduce the fascial tissue into the subannular space. The tissue, once in the subannular space, was allowed to revert toward its original dimensions through its own bias and/or under my manipulation so that it was in an appropriate position subannularly to be secured by the subannular suture loops.

7. As evidenced by the disclosures of U.S. Patent Nos. 4,792,336 and 4,942,875, (copies of which are attached hereto as Exhibit D and E, respectively), the use of autogenous tissue grafts such as fascia lata for augmenting or replacing damaged fibrous connective tissue such as ligaments and tendons was well known in the art, and also by me, prior to the publication date of the abstract. Further, it was well understood that the use of autogenous tissue grafts such as fascia lata provided a natural bridge or platform for the traversal of fibroblasts and other cells involved in tissue repair that are necessary to promote cellular regrowth and enhance healing of a fibrous connective tissue defect or injury.

8. Prior to the publication of my abstract, it was not known to use fascial tissue to repair subannularly a rent, tear or defect in the wall of the annulus fibrosus. I recognized that the placement of the fascial tissue across the rent or tear of the annulus would not only act as a barrier to prevent the migration of the nucleus pulposus from the subannular space, but because of the known biological properties arising from autograft

implantation, the fascial tissue would also advantageously act as a bridge or platform, allowing fibroblasts and normal cells of repair to traverse the aperture and thus facilitate cellular regrowth and healing across the bridge or platform. My ability to promote healing at the annulus injury or defect site satisfied an unmet need to prevent reherniation in patients, a common problem with annulus fibrosus injuries or defects because the limited vasculature of the annulus makes regrowth a challenge.

9. The facts set forth in this abstract evidence the actual reduction to practice of the claimed invention in the United States no later than April 15, 1999.

10. Prior to the reduction to practice of my invention, results of actual surgeries performed by me and extensively followed up under my supervision revealed improved clinical results, where fewer reherniations resulted over the long term using the method according to my invention.

11. Between a time just prior to May 29, 1998 and the actual reduction to practice, I performed twenty-three (23) surgeries practicing the instant invention. During this time, I was reasonably diligent in practicing my invention to perfect the method and the device(s) necessary for the method. These surgeries are listed in Exhibit F, which is a tabulated list prepared under my instruction by clinical research consultant Alice T. Allen. The group "fa" refers to "fascial autograft." Certain dates and other nonrelevant data have been redacted.

12. The data reported in Exhibit F show that I performed a facial autograph surgery to repair the annulus in accordance with my invention at least as early as May 26, 1998. This date, which is prior to the Bao patent filing date of May 29, 1998 evidences the conception of my invention. Following this surgery, I performed twenty-two (22) additional facial autograph surgeries according to my invention up through April 7, 1999. Thus, I believe that I was reasonably diligent in practicing my invention during the period in question.

13. To prove that my invention successfully treated a defect in the annulus fibrosus, I instructed my office staff to contact patients that had undergone surgery performed by me and according to my invention in an effort to collect follow-up data. This data was collected to demonstrate that my invention worked. Moreover, at least some of this data collected was based on surgeries performed prior to May 29, 1998. My office staff was instructed to record certain follow-up data on Patient Information forms such as that shown in Exhibit G, with dates and patient data redacted. One staffer, Tracie Rhoden, was in my employ until September 29, 1998, as shown by office records. I recall Tracie working on gathering this data at the time she left my office. I also recognize the handwriting at the top of Exhibit G as belonging to Tracie. I can therefore accurately confirm at least some of the data collection activity represented by Exhibit G as taking place before September 29, 1998.

14. Following Tracie's departure in September 1998 and under my instruction, clinical research consultant Alice T. Allen took over data collection and continued to do so until actual reduction to practice no later than April 15, 1999. Alice T. Allen

Consulting also calculated all of the recurrence rates which appeared in the abstract submitted on April 15, 1999. At the time I submitted the abstract, the data demonstrated to me that the inventive method worked as I intended.

15. In addition to the abstract submitted on April 15, 1999, I submitted an earlier abstract on September 4, 1998 to the Joint Section on disorders of the spine and Peripheral Nerves (Joint Section) of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons (AANS/CNS) for a poster that I presented at their meeting in Orlando, Florida in February of 1999. A copy of that submission and a confirmatory email evidencing submission is attached hereto as Exhibit H. Alice T. Allen, under my instruction, prepared the abstract and the data contained therein.

16. Alice T. Allen, under my instruction, continued to acquire follow up data on recurrence (reherniation) rates for the surgeries I performed, and continued to perform data collection between the submission of the first abstract in September of 1998 (Exhibit H) and the submission of the abstract in April of 1999 (Exhibit C). This ongoing activity is evident from the fact that the numerical data and reported results are different, and reflect a growing body of data. For example, in Exhibit H, 32 fascial autograft patients are represented, and the data reflects a 3.1% reherniation rate. In Exhibit C, 23 fascial autograft patients are represented, and the data reflects a 4.3% reherniation rate. The data reported in the April 1999 abstract (Exhibit C) benefited from a control group and from a longer follow-up period. I deemed the data reflected in the earlier abstract (September 1998) to be encouraging, but insufficient to me to prove that my invention worked as I intended. The data reflected in the later abstract (April 1999) did just that. Alice T. Allen assisted to collect and analyze the control data as well as the reported data for fascial autograft surgeries.

17. As demonstrated above, data collection and analysis was continuous and reasonably diligent between just prior to May 29, 1998 and April 15, 1999.

18. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Dated: November 16, 2004

By: Joseph C Cauthen III, MD
Joseph C. Cauthen III, MD

CURRICULUM VITAE

JOSEPH C. CAUTHEN, M.D.

FELLOW, AMERICAN COLLEGE OF SURGEONS
DIPLOMATE, AMERICAN BOARD OF NEUROLOGICAL SURGERY
FELLOW, AMERICAN COLLEGE OF SPINE SURGERY
DIPLOMATE, AMERICAN BOARD OF SPINE SURGERY

DATE AND PLACE OF BIRTH: June 22, 1936 Rock Hill, South Carolina

LICENSURE: Kansas, 1967
Florida, 1966
North Carolina, 1962

CERTIFICATION: American Board of Neurological Surgery, 1971

EDUCATION:

Microneurosurgery
University of Zurich, Switzerland
(Professor G. Yasargil)
March 1974

Chief Resident and Instructor, Neurological Surgery
University of Florida College of Medicine
Shands Hospital
Gainesville, Florida
July 1966-June 1967

Resident, Neurological Surgery
University of Florida College of Medicine
July 1963-June 1966

Intern, General Surgery
University of Florida College of Medicine
July 1962-June 1963

M.D.
Duke University School of Medicine
Durham, North Carolina
1963

Bachelor of Science *(Distinguished Military Graduate)*
The Citadel
Charleston, South Carolina
1958

SPECIAL COURSES:

Spine Surgery in the New Millennium
14th International Symposium on Arthroscopic and Endoscopic Surgery
Graduate Hospital and International Society for Minimal Intervention in Spinal Surgery
Philadelphia, Pennsylvania
May 5-6, 2000

Instructor, Posterior Lumbar Interbody Fusion Course,
Jacksonville, Florida
January 16, 1999

Faculty, The Essentials of Spinal Care for the Primary Care Physician
Gainesville, Florida
April 18-19, 1997

Instructor, Surgical Dynamics Surgical Technique Training Program
(Interbody Fusion)
Orlando, Florida
April 5, 1997

Arthroscopic Micro-Endo Cadaver Workshop
Shands Hospital
Gainesville, Florida
December 5, 1994

Arthroscopic Microdiscectomy of the Lumbar Spine
North Florida Regional Medical Center
Gainesville, FL
August 26, 1994

Current Concepts in Spinal Endoscopy
Hands-On Workshop and Symposium
UT Anatomy and Neurobiology Labs
Memphis, TN
June 4, 1994

Thoracoscopy and Laparoscopy of the Spine Course
Texas Back Institute Research Foundation
Presbyterian Hospital, Dallas
February 18-19, 1994

Practical Techniques in Spinal Instrumentation
University of Florida Departments of Neurosurgery and Orthopedaedic Surgery
and The Florida Neurosurgical Society
August 19-23, 1990

SPECIAL COURSES, continued:

Caspar Cervical Spine Stabilization Workshop
Uniformed Services University of the Health Sciences
Bethesda, Maryland
May 24-27, 1990

Taking CNS Trauma into the 90's
Department of Neurological Surgery,
University of Miami School of Medicine
Miami, Florida
March 14-18, 1990

Lumbar Interbody Fusion with Internal Fixation
Temple University School of Medicine
Philadelphia, Pennsylvania
July 1989

Pneumatic Instrumentation for Surgical Procedures
Midas Rex Hands-On Course, Clearwater, Florida
April 11-13, 1987

International Discography Course, Dallas, Texas
March 27-28, 1987

CT-Guided Stereotaxis Practical Course
Congress of Neurological Surgeons and Department of Neurosurgery
University of Florida College of Medicine
Gainesville, Florida
October 1986

Neurosurgery Laser Certification Course
Presbyterian Hospital
Dallas, Texas
October 25-26, 1986

Posterior Lumbar Interbody Fusion Workshop
The Queen's Medical Center and John A. Burns School of Medicine,
University of Hawaii
April 22-24, 1982

Neuropathology
Medical University of South Carolina
March 25-31, 1971

Neuropathology
Armed Forces Institute of Pathology
Walter Reed Army Hospital
May 1971

SPECIAL COURSES, continued:

Neuroradiology
Washington University School of Medicine
St. Louis, Missouri
May 6-10, 1966

Neuro-ophthalmology
University of Miami
Miami, Florida
January 4-8, 1966

Neuro-ophthalmology
University of Miami
Miami, Florida
January 2-7, 1965

MILITARY:

Assistant Chief, Neurosurgical Section
Madigan General Hospital
Tacoma, Washington
September 1969-July 1970

Chief, Neurosurgical Section
71st Evacuation Hospital
Pleiku, Republic of Vietnam
(Bronze Star and Distinguished Service Award)
September 1968-August 1969

APPOINTMENTS:

Active Staff, Neurosurgery
North Florida Regional Medical Center
Gainesville, Florida
July 1973-present

Medical Advisory Board
SPINE
1994-present

Medical Advisory Board
SPINE-HEALTH.COM
October 2000 - present

Active Staff, Neurosurgery
Shands at Alachua General Hospital
Gainesville, Florida
July 1973-1999

Clinical Instructor, Spine Fellowship Program
North Florida Regional Medical Center
Gainesville, Florida
1995-1998

APPOINTMENTS
continued:

Clinical Associate Professor, Division of Neurosurgery
University of Florida College of Medicine and
Shands Hospital
July 1970-September 1999

Consulting Staff, Neurosurgery
Veteran's Administration Hospital
Gainesville, Florida
July 1970-1973

Chief, Neurological Surgery Service
University of Florida College of Medicine
Shands Hospital
January 10, 1973-July 1, 1973

Acting Chief, Division of Neurological Surgery
Department of Surgery
University of Florida College of Medicine
July 1972-July 1973

Assistant Professor, Division of Neurological Surgery
University of Florida College of Medicine
July 1972-July 1973

Instructor, Division of Neurosurgery
Clinical Coordinator, Head Injury Unit
Department of Surgery
University of Kansas Medical Center
July 1967-June 1968

OFFICES HELD:

ProNational Insurance Company
Board of Directors, June 1998-May 1999

Professionals Group Insurance Company
Board of Directors, May 1999 to present

American Board of Spine Surgery, Inc.
Board of Directors, October 1997-present
Secretary-Treasurer, December 1998-present
Chairman, Examination Committee, 1998, 1999, 2000

Alachua County Medical Society
President, 1992-1993
President-elect, 1991-1992
Vice President, 1990-1991
Board of Directors, 1988-present

OFFICES HELD, CONTINUED:

Florida Independent Physicians Association, Inc.
Founding Director, 1993
State President, 1993-present
Region III President, 1993-1994

Florida Medical Association
Chairman, Professional Liability Committee
1992-1996

Florida Medical Political Action Committee (FLAMPAC)
Vice President, 1994-1996
Treasurer, 1992-1993

Florida Neurosurgical Society
President, 1987-1988
President-elect, 1986-1987
Secretary, 1984-1986
Board of Directors, 1982-1988
Chairman, *Ad Hoc* Committee on Legislative Affairs, 1983-1984

Florida Physicians Services, Inc.
Founding Director and Chairman of the Board, 1995-present

North American Spine Society
Program Committee, 1991-1992
Regional Representative, Southeast, 1989
Executive Committee, 1988

North Florida Regional Medical Center
Vice Chairman, Board of Trustees
January 1987-1997
Chief of Medical Staff
1981-1982
Chairman, Executive Committee
1981-1982
Vice Chief of Medical Staff
1978-1980

Physicians Protective Trust Fund
Founding Director, 1976
Vice Chairman, Board of Trustees, 1976-May 1998
Claims Committee, 1976, May 1998

MEMBERSHIPS:

Alachua County Medical Society, 1962-present

American Association of Neurological Surgeons, 1962-present
Ad Hoc Committee on Peer Review
January 1990-January 1991

American College of Surgeons, 1974-present

American Medical Association, 1976-present

Congress of Neurological Surgeons, 1967-present

First Presbyterian Church, Gainesville, Florida
Deacon, 1976-1979

Florida Medical Association, 1963-present

Florida Neurosurgical Society, 1979-present

Foundation for International Education in Neurological Surgery, 1971-1980

Gainesville Rotary Club, Gainesville, Florida
Board of Directors, 1982-1984

North American Spine Society, Charter Member, 1988-present

Society of Neurosurgical Anesthesia and Neurological Supportive Care, 1983

Southern Neurosurgical Society, 1974-1980

PUBLICATIONS:

Robert R. Hacker, Joseph C. Cauthen, S. Griffith: A Prospective Randomized Multicenter Clinical Evaluation of an Anterior Cervical Fusion Cage. Spine 2000 25: 2646-2655.

Joseph C. Cauthen, Richard S. Kinard, James B. Vogler, Donald E. Jackson, Oscar DePaz, Oregon Hunter, Lori Wasserburger, Erik Weitzel, and Virginia Williams: Outcome Analysis of Non-instrumented Anterior Cervical Discectomy and Interbody Fusion in 348 Patients. Spine 23(2):188-192, 1998.

Joseph C. Cauthen, Editor: Lumbar Spine Surgery: Indications, Techniques, Failures and Alternatives. Baltimore, Williams & Wilkins, 1983, First Edition. 1987, Second Edition.

E. Scott Medley and Joseph C. Cauthen: Neurosurgical Disorders. In Family Medicine-Principles and Practice, Second Edition. New York, Springer-Verlag, 1983, Chapter 65, p. 1496.

C. C. Carlton and Joseph C. Cauthen: Vascular malformation of the choroid plexus. Accepted by Archives of Pathology 99(5):286-8, 1974.

PUBLICATIONS,
CONTINUED:

J. R. Mozingo and Joseph C. Cauthen: Vaginal perforation by a Raimondi peritoneal catheter in an adult. Surgical Neurology 2:195-196, May 1974.

C. J. Whang, Joseph C. Cauthen, Francisco Garcia-Bengochea: Successful treatment of ventriculitis by continuous intraventricular lavage with gentamycin solution. Surgical Neurology 2:91-94, 1974.

Robert Watson, Kenneth Heilman, Joseph C. Cauthen, Frederick A. King: Neglect following cingulectomy. Accepted by Archives of Neurology, 1973.

Edwin E. MacGee, Joseph C. Cauthen, Charles E. Brackett: Meningitis following acute traumatic CSF fistula. Journal of Neurosurgery 33:312-316, 1970.

Joseph C. Cauthen, Stanley R. Nelson, Robert F. Hustead, Richard Saylor, John Overman: Spinal fluid pyruvate and lactate levels. Archives of Neurology 22:463-469, 1970.

Joseph C. Cauthen, L.P. McLaurin, Malcolm T. Foster, Lamar Roberts: Spinal cord compression secondary to extramedullary hematopoiesis in two brothers. Journal of Neurosurgery 24: 529-531, 1968.

Joseph C. Cauthen: Introducer for Pudenz tubing in ventriculo-atrial shunts. American Journal of Surgery 115:738-739, 1968.

Leonard Reaves III, Joseph C. Cauthen, Francisco Garcia-Bengochea: Psychogenic diabetes insipidus: A case report with description of certain differential diagnostic procedures. Journal of Neurosurgery 23:394-397, 1965.

ABSTRACTS/PRESENTATIONS:

Joseph C. Cauthen: *Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique.*. Oral Presentation. World Spine Conference 1. Berlin, August 28, 2000.

Joseph C. Cauthen: A Prospective Randomized Multicenter Clinical Evaluation of an Anterior Cervical Fusion Cage. Oral Presentation. World Spine Conference 1. Berlin, August 28, 2000.

Joseph C. Cauthen: *Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique.* Poster Presentation. American Association of Neurological Surgeons and Congress of Neurological Surgeons, Section on Disorders of the Spine and Peripheral Nerves. Lake Buena Vista, FL. February 10-13, 1999.

Joseph C. Cauthen, Richard S. Kinard, James B. Vogler, Donald E. Jackson, Oscar DePaz, Oregon Hunter, Lori Wasserburger, Erik Weitzel, and Virginia Williams: *Is Non-instrumented Anterior Cervical Discectomy and Interbody Fusion Effective? A Twenty-one Year Retrospective Outcome Analysis in 307 Patients.* Poster Presentation. Cervical Spine Research Society Meeting. The Breakers, Palm Beach, Fl, December 5-7, 1996.

Joseph C. Cauthen, Richard S. Kinard, James B. Vogler, Donald E. Jackson, Oscar DePaz, Oregon Hunter, Lori Wasserburger, Erik Weitzel, and Virginia Williams: *A Twenty-one Year Retrospective Outcome Analysis of Anterior Cervical Discectomy and Interbody Fusion ACDF) in 236 Patients: Is It Effective?* Poster Presentation. Congress of Neurological Surgeons Annual Meeting. September 28-October 3, 1996, Montreal, Quebec, Canada.

Joseph C. Cauthen, Richard S. Kinard, James B. Vogler, Donald E. Jackson, Oscar DePaz, Oregon Hunter, Lori Wasserburger, Erik Weitzel, and Virginia Williams: *Non-instrumented Anterior Cervical Discectomy and Interbody Fusion (ACDF): A Twenty-year Retrospective Outcome and Multi-variant Analysis.* Read before the North American Spine Society Annual Meeting, October 21, 1994.

Panel moderator, Workshop on Cervical Spine Reconstruction, North American Spine Society Annual Meeting, Boston, Massachusetts, July 1992.

Microlumbar Disc Removal: Review of 100 Cases. Read before the Florida Neurosurgical Society, May 1982.

Program director, Neurology-Neurosurgery Seminar, 1981: Update for the Primary Care Physician. Gainesville, Florida, 1981.

Panel moderator, Medico-legal Seminar, Miami, Florida 1980.

Therapeutic Barbiturate Coma. Read before the North Florida Regional Medical Center Staff, 1980.

Cerebral Neoplasms. Read before the Citrus County Memorial Hostital Staff, 1980.

Cerebral Aneurysms. Read before the Citrus County Memorial Hospital Staff, 1980.

Program Director: Lumbar Spine Surgery Seminar, Gainesville, Florida, 1980.

Barbiturate Coma. Read before the Florida Neurosurgical Society, 1980.

Relief of Chronic Lumbar Pain by Radiofrequency Facet Denervation. Read before the 29th Annual Florida Workmen's Compensation Educational Conference, October 11, 1974.

Normal Pressure Hydrocephalus, Pre- and Postoperative Psychological Test Data. Read before the Florida Neurosurgical Society, November 1974.

Peripheral Nerve Stimulation in Chronic Pain States. Read before the Pain Symposium, Minneapolis, Minnesota, December 1973.

Cerebrospinal Fluid Lactate Levels in Experimental Hyperventilation. Read before Congress of Neurological Surgeons, Pre-Convention, Honolulu, Hawaii, October 1973.

Microsurgical Removal of Pineal Teratoma. Read before Microneurosurgery Symposium, Cincinnati, Ohio, May 1972.

Management of Cerebral Trauma. Read before Florida Neurosurgical Society, August 1971.

EKG Monitoring during Ventriculo-atrial Shunt Placement. Read before the Florida Neurosurgical Society, August 1966.

Spinal Cord Compression Secondary to Hematopoiesis. Read before the Congress of Neurological Surgeons, October 1966.

Transoral Resection of Odontoid for Platybasia. Read before the Florida Neurosurgical Society, September 1965.

DESCRIPTION

SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT

Field of the Invention

The invention generally relates to a surgical method of intervertebral disc wall reconstruction with a related annulus stent augmenting the repair. The effects of said reconstruction is restoration of disc wall integrity and reduction of the failure rate (3-21%) of a common surgical procedure (disc fragment removal or discectomy). This surgical procedure is performed about 390,000 times annually in the United States.

Background of the Invention

The spinal column is formed from a number of vertebrae, which in their normal state are separated from each other by cartilaginous intervertebral discs. The intervertebral disc acts in the spine as a crucial stabilizer, and as a mechanism for force distribution between the vertebal bodies. Without the disc, collapse of the intervertebral space occurs in conjunction with abnormal joint mechanics and premature development of arthritic changes.

The normal intervertebral disc has an outer ligamentous ring called the annulus surrounding the nucleus pulposus. The annulus binds the adjacent vertebrae together and is constituted of collagen fibers that are attached to the vertebrae and cross each other so that half of the individual fibers will tighten as the vertebrae are rotated in either direction, thus resisting twisting or torsional motion. The nucleus pulposus is constituted of loose tissue, having about 85% water content, which moves about during bending from front to back from side to side.

As people age the annulus tends to thicken, desicate, and become more rigid. The nucleus pulposus, in turn becomes more viscous and less fluid and sometimes even dehydrates and contracts. The annulus also becomes susceptible to fracturing or fissuring. These fractures tend to occur all around the circumferences of the annulus and can extend

from both the outside of the annulus inwards, and the interior outward. Occasionally, a fissure from the outside of the annulus meets a fissure from the inside and results in a complete vent through the annulus fibrosis. In situations like these, the nucleus pulposus may extrude out through the intervertebral disc. The extruded material, in turn, can impinge on the spinal cord or on the spinal nerve rootlet as it exits through the intervertebral disc foramen, resulting in a ruptured disc.

In the event of annulus rupture, the inner-nucleus component migrates along the path of least resistance forcing the fissure to open further, allowing migration of the nucleus pulposus through the wall of the disc, with resultant nerve compression and leakage of chemicals of inflammation into the space around the adjacent nerve roots supplying the extremities, bladder, bowel and genitalia. The usual effect of nerve compression and inflammation is intolerable back or neck pain, radiating into the extremities, with accompanying numbness, weakness, and in late stages, paralysis and muscle atrophy, and/or bladder and bowel incontinence. Additionally, injury, disease or other degenerative disorders may cause one or more of the intervertebral discs to shrink, collapse, deteriorate or become displaced, herniated, or otherwise damaged.

The surgical standard of care for treatment of herniated, displaced or ruptured intervertebral discs is fragment removal and nerve decompression, without a requirement to reconstruct the annular wall. While results are currently acceptable, they are not optimal. Various authors report 3.1-21% recurrent disc herniation, representing a failure of the primary procedure and requiring re-operation for the same condition. A conservative estimated 10% recurrence rate results in 39,000 re-operations in the United States each year.

An additional method of relieving the symptoms is annuloplasty, involving the heating of sub annular zones in the non-herniated painful disc, seeking pain relief, but makes no claim of reconstruction of the ruptured, discontinuous annulus wall.

There is currently no method of annulus reconstruction either primarily, or augmented with an annulus stent.

Brief Summary of the Invention

The present invention provides a method and related materials for reconstruction of displaced, herniated, ruptured, or otherwise damaged intervertebral discs.

In a preferred form, one or more mild biodegradable surgical sutures are placed at about equal distance along the sides of a pathologic aperture in the ruptured disc wall (annulus) or along the sides of a surgical incision in the weakened, thinned disc annulus.

Sutures are then tied in such fashion as to draw together the sides of the aperture, effecting reapproximation or closure of the opening, to enhance natural healing and subsequent reconstruction by natural tissue (fibroblasts) crossing the now surgically narrowed gap in the disc annulus.

A 25-30% reduction in the rate of recurrence of disc nucleus herniation through this aperture, has been achieved using this method.

In another embodiment, the method can be augmented by placement of a patch of human muscle fascia acting as a bridge in and across the aperture, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

A 30-50% reduction in the rate of recurrence of disc herniation has been achieved using the aforementioned apertures with this embodiment.

Having demonstrated that human muscle fascia (the membrane covering the muscle) is adaptable for annular reconstruction, other biocompatible membranes can be employed as a bridge or stent, or barrier to subsequent migration of the disc nucleus through the aperture, such as medical grade biocompatible fabric, biodegradable polymeric sheets, or form fitting or non-form fitting fillers for the cavity created by removal of the disc nucleus in the course of the previous mentioned operation, discectomy. The prosthetic material can be placed in and around the intervertebral space, created by removal of the degenerated disc fragments.

Brief Description of the Drawings

Figure 1 shows a perspective view of the annulus stent.

Figure 2 shows a front view of the annulus stent.

Figure 3 shows a side view of the annulus stent.

Figure 4A-4C show a front view of various alternative embodiments of the annulus stent.

Figure 5A-5B shows the alternative embodiment of a pyramid shaped annulus stent.

Figure 6A-6B shows the alternative embodiment of a coned shaped annulus stent.

Figure 7 shows the primary closure of the opening in the disc annulus, without an intervertebral or subannular stent.

Figure 8A-8B shows the primary closure with a stent in generic form.

Figure 9A-9D show the annulus stent being inserted into the disc annulus.

Figure 10 shows a method of suturing the annulus stent into the disc annulus, utilizing sub annular fixation points.

Detailed Description of the Invention

The present invention provides a method and related materials for reconstruction of displaced, herniated, ruptured, or otherwise damaged intervertebral discs.

In an embodiment of the present invention, as shown in Figure 7, a damaged annulus 42 is repaired by use of surgical sutures 40. One or more surgical sutures 40 are placed at about equal distances along the sides of a pathologic aperture 44 in the ruptured annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 in such a fashion that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable.

Additionally, to repair a weakened or thinned disc annulus 42, a surgical incision is made along the weakened or thinned region of the annulus 42 and one or more surgical sutures 40 are placed at about equal distances along the sides of the incision. Reapproximation or closure of the incision is accomplished by tying the sutures 40 in such a fashion that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural healing and subsequent reconstruction by the natural

tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable.

In an alternative embodiment, the method can be augmented by the placement of a patch of human muscle fascia in and across the aperture 44. The patch acts as a bridge in and across the aperture, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

In a further embodiment, as shown in Figure 8, a biocompatible membrane can be employed as an annulus stent 10, being placed in and across the aperture 44. The annulus stent 10 acts as a bridge in and across the aperture 44, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture 44.

In a preferred embodiment, as shown in Figures 1-3, the annulus stent 10 comprises a centralized vertical extension 12, with an upper section 14 and a lower section 16. The centralized vertical extension 12 is trapezoid in shape through the width and may be from about 8mm -12mm in length.

Additionally, the upper section 14 of the centralized vertical extension 12 may be any of a number of different shapes, as shown in Figures 4A and 4B, with the sides of the upper section 14 being curved or with the upper section 14 being circular in shape. Furthermore, the annulus stent 10 may contain a recess, between the upper section 14 and the lower section 16, enabling the annulus stent 10 to form a clean fit with the edges of the aperture 44.

The upper section 14 comprises an orifice 18, through which sutures, tension bands, staples or any other type of fixation device known in the art may be passed, to affix the annulus stent 10 to the disc annulus 44.

In an alternative embodiment, the upper section 14 may be perforated such that sutures, tension bands, staples or any other type of fixation device known in the art may be passed, to affix the annulus stent 10 to the disc annulus 44.

The lower section 16 comprises a pair of lateral extensions, a left lateral extension 20 and a right lateral extension 22. The lateral extensions 20 and 22 comprise a inside edge

24 an outside edge 26, an upper surface 28, and a lower surface 30. The lateral extensions 20 and 22 have a constant thickness throughout. The inside edge 24 is attached to the lower section 16 and is about the same length as the lower section 16. The outside edge 26 can be about 8mm - 16mm in length. The inside edge 24 and the lower section 16 meet to form a horizontal plain, perpendicular to the centralized vertical extension 12. The upper surface 28 of the lateral extensions 20 and 22 form an angle of 0°-60° below the horizontal plain. The width of the annulus stent 10 may be from about 3mm-5mm.

Additionally, the upper surface 28 of the lateral extensions 20 and 22 may be barbed for fixation to the inside surface of the disc annulus 40 and to resist expulsion through the aperture 44.

In an alternative embodiment, as shown in Figure 4B, the lateral extensions 20 and 22 have a greater thickness at the inside edge 24 then at the outside edge 26.

In a preferred embodiment, the annulus stent 10 is a solid unit, formed from one of the flexible resilient biocompatible or bioresorbable material well know in the art.

Alternatively, the annulus stent may be made from:

a porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus fibrosus as disclosed in, for example, U.S. Patent Nos. 5,108,438 (Stone) and 5258,043 (Stone);

a strong network of inert fibers intermingled with a bioresorbable (or biosabsorable) material which attracts tissue ingrowth as disclosed in, for example, U.S. Patent No. 4,904,260 (Ray et al.);

a biodegradable substrate as disclosed in, for example, U.S. Patent No. 5,964,807 (Gan at al.); or

a expandable polytetrafluoroethylene (ePTFE), as used for conventional vascular grafts, such as those sold by W.L. Gore and Associates, Inc. under the trademarks GORE-TEX and PRECLUDE, or by Impra, Inc. under the trademark IMPRA.

Furthermore, the annulus stent 10, may contain hygroscopic material, for a controlled limited expansion of the annulus stent 10 to fill the evacuated disc space cavity.

Additionally, the annulus stent 10 may comprise materials to facilitate regeneration of disc tissue, such as; bioactive silica based materials which assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

In further embodiments, as shown in Figures 5-6, the left and right lateral extensions 20 and 22 join to form a solid pyramid or cone. Additionally, the left and right lateral extensions 20 and 22 may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral extensions 20 and 22 to be compressed for insertion into aperture 44, then to expand conforming to the shape of the annulus' 42 inner wall.

Alternatively, a compressible core may be attached to the lower surface 30 of the lateral extensions 20 and 22, forming a pyramid , cone, trapezoid, wedge, or bullet shape. The compressible core may be made form one of the biocompatible or bioresorbable resilient foams well known in the art. The compressible core allows the lateral extensions 20 and 22 to be compressed for insertion into aperture 44, then to expand conforming to the shape of the annulus' 42 inner wall.

In a preferred method of use, as shown in Figures 9A-9D, the lateral extensions 20 and 22 are compressed together for insertion into the aperture 44 of the disc annulus 40. The annulus stent 10 is then inserted into the aperture 44, where the lateral extensions 20 and 22 expand, with the upper surface 28 contouring to the inside surface of the disc annulus 40. The upper section 14 is positioned within the aperture 44 so that the annulus stent 10 may be secured to the disc annulus 40. using means well known in the art.

In an alternative method, where the length of the aperture 44 is less than the length of the outside edge 26 of the annulus stent 10, the annulus stent 10 must be inserted laterally into the aperture 44. The lateral extensions 20 and 22 are compressed, and the annulus stent 10 is laterally inserted into the aperture 44. The annulus stent 10 is then rotated inside the disc annulus 40, such that the upper section 14 is pulled back through the aperture 44. The lateral extensions 20 and 22 are then allowed to expand, with the upper surface 28 contouring to the inside surface of the disc annulus 40. The upper section 14 is positioned within the

aperture 44 such that the annulus stent 10 may be secured to the disc annulus, using means well known in the art.

In an alternative method of securing the annulus stent 10 in the aperture 44, as shown in Figure 10, a first surgical screw 50 and second surgical screw 52, with eye holes 53 located at the top of the screws 50 and 52, are opposingly inserted into the adjacent vertebrae 54 and 56 below the annulus stent 10. After insertion of the annulus stent 10 into the aperture 44 a suture is passed down though the disc annulus 40, adjacent to the aperture 44, through the eye hole 53 on the first screw 50 then back up through the disc annulus 40 and through the orifice 18 on the annulus stent 10. This is repeated for the second screw 52, after which the suture is secured. One or more surgical sutures 40 are placed at about equal distances along the sides of the aperture 44 in the disc annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 in such a fashion that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable. This method should decrease the strain on the disc annulus 40 adjacent to the aperture 44, precluding the tearing of the sutures through the disc annulus 40.

It is anticipated that fibroblasts will engage the fibers of the polymer or fabric of the intervertebral disc stent, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

All patents referred to or cited herein are incorporated by reference in their entirety to the extent they are not inconsistent with the explicit teachings of this specification, including; U.S. Patent No. 5,108,438 (Stone), U.S. Patent No. 5,258,043 (Stone), U.S. Patent No. 4,904,260 (Ray et al.), U.S. Patent No. 5,964,807 (Gan et al.), U.S. Patent No. 5,849,331 (Ducheyne et al.), U.S. Patent No. 5,122,154 (Rhodes), U.S. Patent No. 5,204,106 (Schepers at al.), U.S. Patent No. 5,888,220 (Felt et al.), U.S. Patent No. 5,376,120 (Sarver et al.).

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and preview of this application and the scope of the appended claims.

Abstract of the Disclosure

A surgical method of repair and reconstruction of the spinal disc wall (annulus) after surgical invasion or pathologic rupture, incorporating suture closure, or stent insertion and fixation, designed to reduce the failure rate of conventional surgical procedures on the spinal discs.

The design of the spinal disc annulus stent allows ingrowth of normal cells of healing in an enhanced fashion strengthening the normal reparative process.

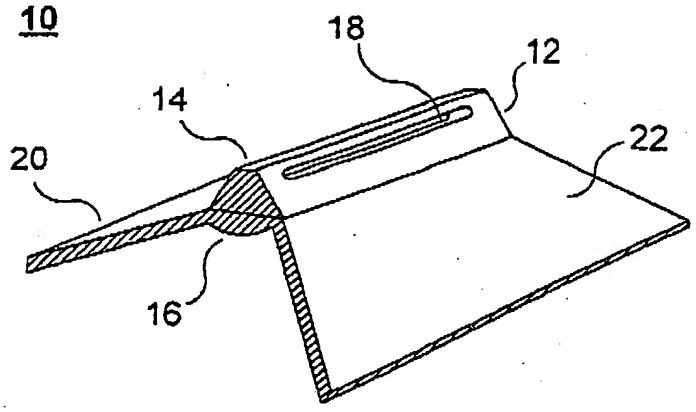

FIG. 1

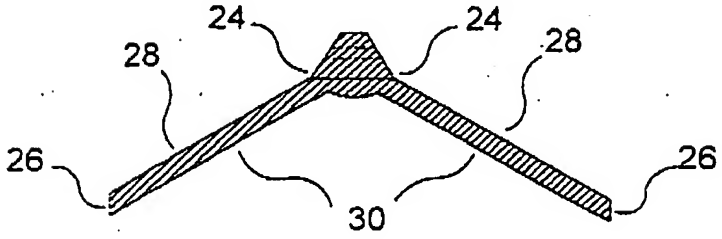

FIG. 2

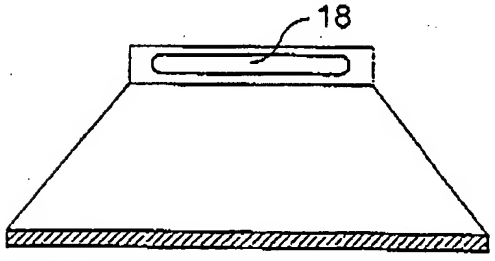

FIG. 3

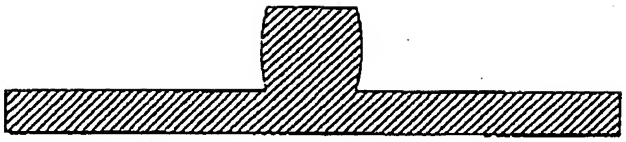

FIG. 4A

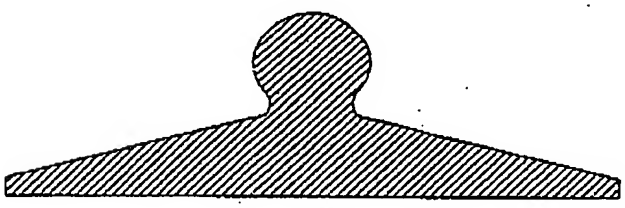

FIG. 4B

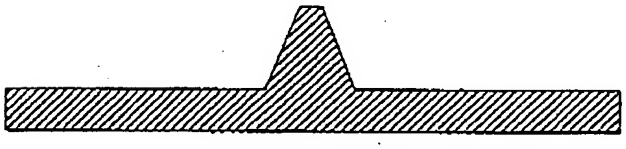

FIG. 4C

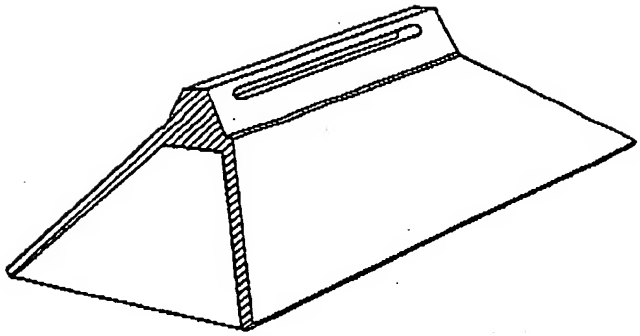

FIG. 5A

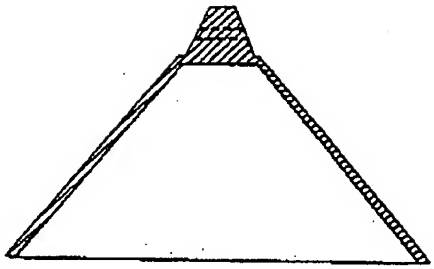

FIG. 5B

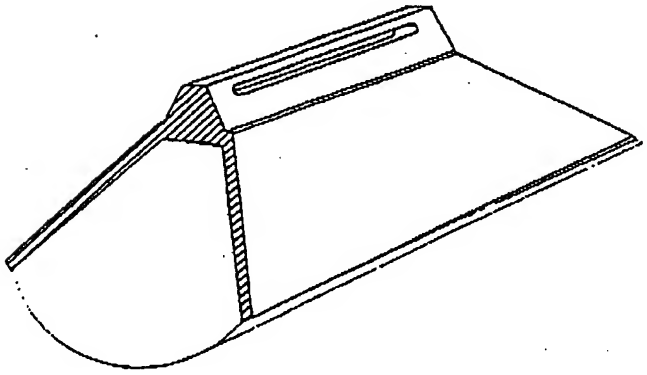

FIG. 6A

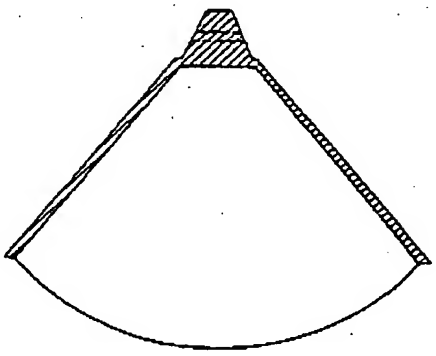

FIG. 6B

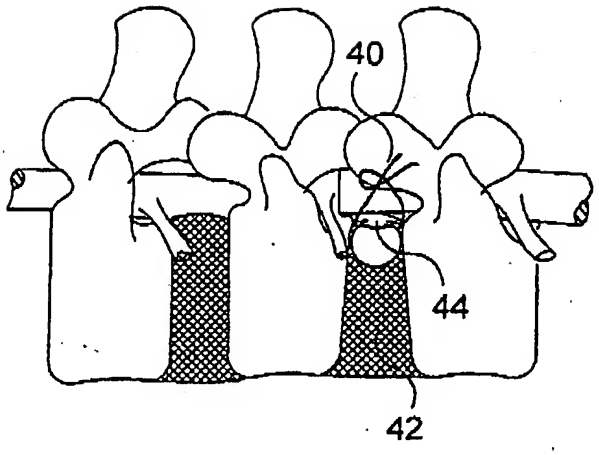

FIG. 7

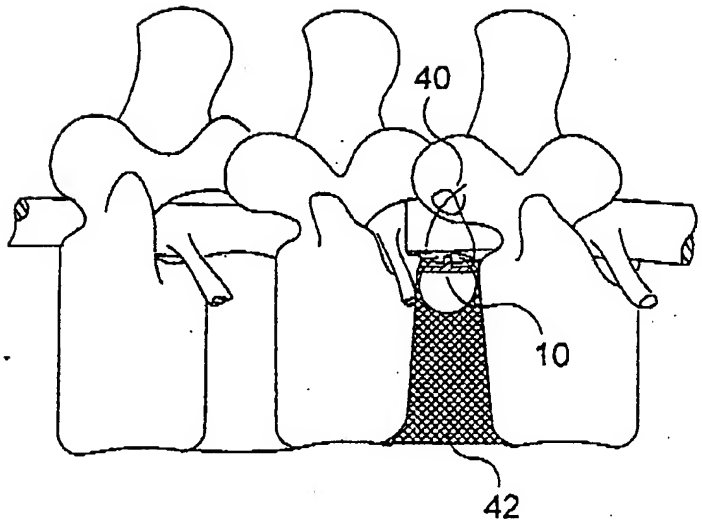

FIG. 8A

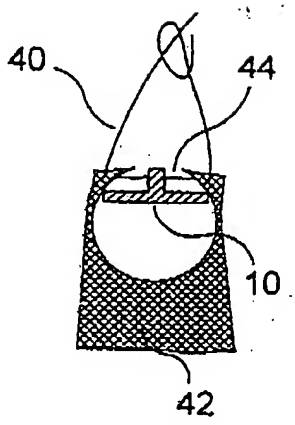

FIG. 8B

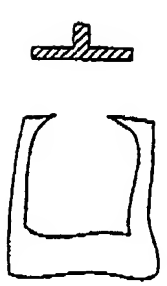

FIG. 9A

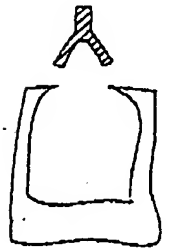

FIG. 9B

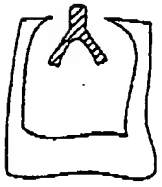

FIG. 9C

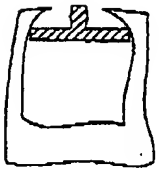

FIG. 9D

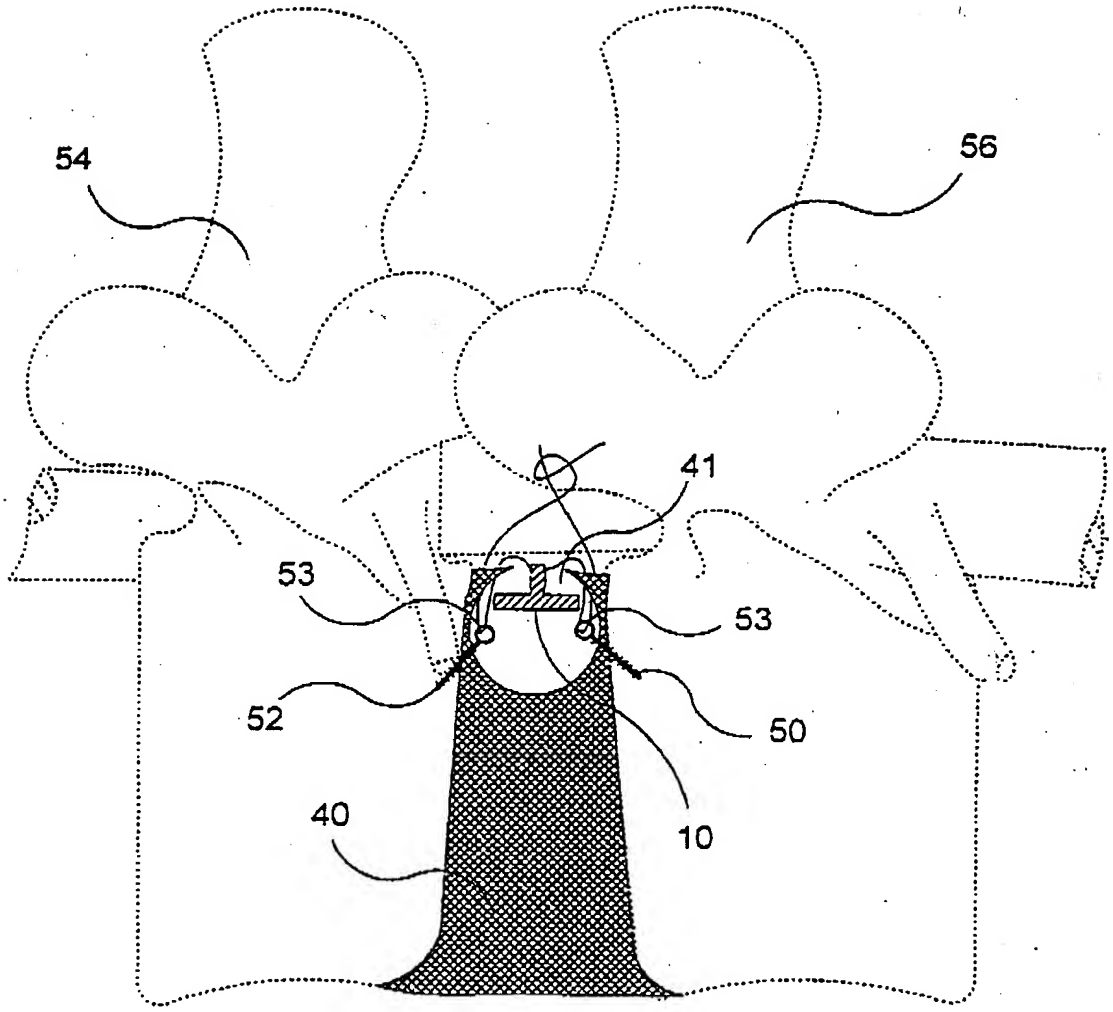

FIG. 10

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TITLE: Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: A New Technique

AUTHORS: Joseph Cauthen, MD

ABSTRACT:
Introduction. Since nuclear herniation occurs through an annular defect, intuition suggests that the rate of reherniation following initial lumbar discectomy can be reduced by closing the annular defect. Methods. Modification of the standard technique incorporates: (1) slit annulotomy and, following disc fragment removal, (2) annuloplasty using one or two sutures alone or (3) adding subannular fascial autograft prior to suture closure of the annular defect. Technique. The procedure employs standard unilateral laminotomy and micro-operative technique for retrieval of herniated nuclear fragments, either in the epidural or subannular spaces. If an annular defect is present, extruded and interspace fragments are removed as required, preparatory to annulus closure. In the intact attenuated annulus, slit annulotomy is performed utilizing a 5-8 mm sharp incision at annular midpoint equidistant from endplates. Annuloplasty requires placement of 4-0 absorbable sutures on half-circle needles equidistant along the annulotomy opening and microsurgical knot-tying technique. A fascial autograft is secured in the subannular loop of the sutures used to close the annulotomy incision. Results. Total annuloplasties performed: 41 one suture, 45 two sutures, and 48 fascial autografts. With minimum one-year follow-up, results are: one suture (reherniation in 9/41=22.0%); two or more sutures (5/44=11.4%); multiple sutures with fascial autograft (1/23=4.3 %); controls (26/118=22.0%). Discussion. Literature reports of symptomatic recurrent disc herniation requiring reoperation are 1.3-21% (Branch CL. Clin. Neurosurg.

1995;18:252-267). Conclusion. This series suggests that microsurgical annular reconstruction with at least two sutures reduces the rate of reherniation, and use of fascial autograft provides additional benefit.

AWARD:

CAUTHEN ANNULOPLASTY RESEARCH PATIENTS*

Group: [redacted] fa=fascial autograft

IDCODE	Annulo_Control	Group	Date of Surgery
[redacted]	annulo	fa	05/26/1998
	annulo	fa	06/10/1998
	annulo	fa	06/10/1998
	annulo	fa	06/12/1998
	annulo	fa	06/29/1998
	annulo	fa	07/10/1998
	annulo	fa	07/29/1998
	annulo	fa	09/02/1998
	annulo	fa	09/16/1998
	annulo	fa	09/28/1998
	annulo	fa	10/16/1998
	annulo	fa	10/26/1998
	annulo	fa	11/16/1998
	annulo	fa	11/30/1998
	annulo	fa	01/15/1999
	annulo	fa	01/25/1999
	annulo	fa	01/27/1999
	annulo	fa	02/08/1999
	annulo	fa	03/05/1999
	annulo	fa	03/05/1999
	annulo	fa	03/12/1999
	annulo	fa	04/02/1999
	annulo	fa	04/07/1999
[redacted]	[redacted]	[redacted]	[redacted]

Patient Info
Patient Name [redacted]
Address

2/F6

Telephone
SS#

DOB [redacted] **CONFIDENTIAL**

Surgery Information
Diagnosis L disk hernia, L4-L5, central and left

Surgery Date [redacted]
Procedure ll, mF, pd. gnrd, L4-L5 left; slit annulotomy + annuloplasty with fascial subannular autograft, L4-L5 left.

Complications (check if applicable) (Date Resolved)

- ___ Infections
- ___ Weakness/Numbness in leg or foot
- ___ Prolonged Leg Pain (3 months)
- ___ Sub Q Blood Loss or Fluid Collection
- X Other (Describe) Clear pain [redacted]

Report [redacted] No Recurr [redacted]

Time in: 12:15 pm
out: 2:10 pm
EBL: 0 cc

Hospital UFR
#Nights in Hospital 1

Hospital # 295744
605

Additional Surgeries (use additional page if needed)
Diagnosis CDDD; cerv. spinal stenosis C4-5, C5-6, C6-7
cerv. nerve comp. C5, C6, C7

Surgery Date 2/29/99
Procedure Cerv. diskect. anterior w/decomp. of the spinal cord and nerve roots; C4-5, C5-6 & C6-7. Arthrodesis, ant. interbody technique C4-5, C5-6, C6-7. harvesting. fashioning (R) iliac crest tricortical bone graft. (3); Spinal instrumen. C4-C7, (R) Blackstone ant. cerv. plate

Complications (check if applicable) (Date Resolved)

- ___ Infections
- ___ Weakness/Numbness in leg or foot
- ___ Prolonged Leg Pain (3 months)
- X Sub Q Blood Loss or Fluid Collection
- X Other (Describe) Progressive dysphonia [redacted]

Hospital NFRMC
#Nights in Hospital 3

Hospital # 000654

[redacted] Annulo: F/6

NAME: _____ **CONFIDENTIAL**

PLEASE CIRCLE THE CORRECT ANSWER

1. **Were you satisfied with the results of your back surgery?**
   (1.) Extremely Satisfied-I can do almost everything I used to do.
   2. Satisfied-I'm better off now than I used to be.
   3. Slightly Satisfied-I see little improvement in my condition.
   4. Not Satisfied-I shouldn't have had the operation.

2. **Did you recover to a normal lifestyle after the operation?**
   1. Recovered Completely-I can do anything I could do before I had pain.
   (2.) Partially Recovered-I can do most everything I used to.
   3. Slightly Recovered-I can't live normally anymore.
   4. Not Recovered-I'm worse off now than I was.

3. **How long did it take you to recover from the operation?**
   A. 2 weeks B. 2 months (C.) 6 months
   D. 1 year E. 2 years F. 5 years

4. **Please rate your current overall activity level.**
   (1.) Excellent-I'm very active.
   (2.) Good-I'm fairly active.
   3. Fair-My pain limits my activity level.
   4. Poor-My pain severely limits my activity level.

5. **Did you work before your surgery?** 1. Yes 2. (No)

6. **Did you return to work after the surgery?** 1. Yes 2. No
   If Yes then When? _____

7. **Please rate your degree of job satisfaction when the accident occurred.**
   1. Extremely Satisfied.
   2. Satisfied-It's a good job.
   3. Slightly Satisfied-Work was a chore.
   4. Not Satisfied-I did the work/I had no choice.

8. **Were your medical expenses paid by Workman's Comp. Ins.?** 1. Yes 2. (No)
   If Yes, on what dates were the claims settled? _____ Not settled _____

9. **Did you receive disability payments from other sources?** 1. Yes 2. (No)
   If Yes, on what dates were the claims settled? _____ *Not settled* _____

10. **Please rate your job satisfaction after returning to work.**
    1. Extremely Satisfied.
    2. Satisfied-It's a good job.
    3. Slightly Satisfied-Work is a chore.
    4. Not Satisfied-I work because I have to.

11. **If you chose 3 or 4 on question 10, do you feel that the problems with your job are a direct result of the operation?** 1. Yes 2. No

12. **Did your accident result in a law suit?** 1. Yes 2. (No)
    If Yes, date settled _____ *not settled yet* _____

13. **Please describe your pain after you recovered from the surgery.**
    1. No pain-The pain I had before the operation was totally relieved.
    (2.) Slight pain-I experienced much less pain than before the operation.
    3. Not much better-I have about the same pain as before the operation.
    4. Worse-The pain is worse now than before the surgery.

[redacted]

14. Where was your pain BEFORE surgery and AFTER you recovered.

Low Back and hips, pain down legs, after I recovered there was No pain.

15. Please list your present medications and the amount that you take.

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Medication Dose How many times a day?

The Medication I am on now is because of new injury to low back and neck. ([redacted])

(write on back if necessary)

16. Please answer Yes or No for each statement below:
Did you smoke before the operation? 1. Yes 2. (No)
Did you smoke after the operation: 1. Yes 2. (No)

17. How many doctors did you see for your back (after) the surgery? only Dr. Caulton

18. Have you had any more back surgeries? 1. Yes 2. (No)
If Yes, How many and when?

Date	Performed by (Doctor's name)	At What Hospital?	Same Level?

19. Did the subsequent operations help you problem? 1. Yes 2. No

20. Education:
1. Did not graduate high school or GED ____
2. High school or GED ____
(3.) Trade school or associate degree ____
4. College degree ____
5. Advanced degree ____

Dr. Caulton you are the best!!

F/G

Subject: Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique
Date: Fri, 04 Sep 1998 14:35:21 GMT
From: abstracts@neurosurgery.org
To: aliallen@mindspring.com

<P>Confirmation of Online Abstract Submission</P>

<P>AANS/CNS Section on Disorders of the Spine & Peripheral Nerves Annual Meeting</P>

<P>TITLE: Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Micro

<P>AUTHORS: Joseph C. Cauthen, MD</P>

<P>ABSTRACT:</P>

<P> INTRODUCTION. Any new method offering a prospect of lowering discal reherni
Modification of the standard technique incorporates: (1) slit annulotomy and, f
TECHNIQUE. The procedure employs standard unilateral laminotomy and micro-oper
RESULTS. Literature reports of symptomatic recurrent disc herniation requiring
CONCLUSION. Microsurgical annular reconstruction following lumbar microdiscect
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Microsurgical Annular Reconstruction (Annuloplasty) Following Lumbar Microdiscectomy: Preliminary Report of a New Technique

Joseph C. Cauthen, M.D.

Introduction. Any new method offering a prospect of lowering discal reherniation rates and subsequent reoperation after lumbar discectomy deserves consideration by spine surgeons. An operative technique to reconstruct the annulus following lumbar microdiscectomy has been developed. Since nuclear herniation occurs through an annular defect, intuition suggests that the rate of reherniation following initial discectomy can be reduced by closing the annular defect.

Modification of the standard technique incorporates: (1) slit annulotomy and, following disc fragment removal, (2) annuloplasty using one or two sutures alone or (3) adding subannular fascial autograft prior to suture closure of the annular defect.

Technique. The procedure employs standard unilateral laminotomy and micro-operative technique for retrieval of herniated nuclear fragments, either in the epidural or subannular spaces. If an annular defect is present, extruded and interspace fragments are removed as required, preparatory to annulus closure. In the intact attenuated annulus, slit annulotomy is performed utilizing a 5-8 mm sharp incision at annular midpoint equidistant from endplates. Annuloplasty requires placement of 4-0 absorbable sutures on half-circle needles equidistant along the annulotomy opening and microsurgical knot-tying technique. A fascial autograft is secured in the subannular loop of the sutures used to close the annulotomy incision. With experience, additional operative time required is less than thirty minutes.

Results. Literature reports of symptomatic recurrent disc herniation requiring reoperation are 1.3-21% (Branch CL. *Clin. Neurosurg.* 1995;18:252-267). To date, annuloplasty results are: one suture (reherniation in 7/40=17.5%); two or more sutures (2/42=4.7%); multiple sutures with fascial autograft (1/32=3.1 %).

Conclusion. Microsurgical annular reconstruction following lumbar microdiscectomy may prove valuable as this technique continues to evolve.

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